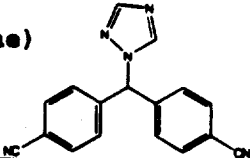


**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER: NDA 20/726/S-006

CHEMISTRY REVIEW(S)

CHEMIST'S REVIEW#1		1. ORGANIZATION HFD-150 DODP		2. NDA NUMBER 20-726	
3. NAME AND ADDRESS OF APPLICANT (City and State) Novartis Pharmaceuticals Corporation 59 Route 10 East Hanover, New Jersey 07936-1080				4. AF NUMBER	
5. SUPPLEMENT (S) NUMBER(S) DATE(S)				SE1-006 7-11-2000	
6. NAME OF DRUG Femara		7. NONPROPRIETARY NAME Letrozole Tablets		9. AMENDMENTS DATES	
8. SUPPLEMENT PROVIDES FOR: a new indication in the first-line treatment of postmenopausal women with advanced breast cancer.				12. RELATED IND/NDA/DMF	
10. PHARMACOLOGICAL CATEGORY Antineoplastic		11. HOW DISPENSED RX <input checked="" type="checkbox"/> OTC		13. DOSAGE FORM(S) Tablet	
14. POTENCY 2.5 mg/tablet		15. CHEMICAL NAME AND STRUCTURE 4,4'-(1H-1,2,4-Triazol-1-ylmethylene) benzonitrile C ₁₇ H ₁₁ N ₃ , NW 285.31			
				16. RECORDS AND REPORTS CURRENT YES <input checked="" type="checkbox"/> NO REVIEWED YES <input checked="" type="checkbox"/> NO	
17. COMMENTS This is an efficacy supplement for a new indication in the first-line treatment of postmenopausal women with advanced breast cancer. This drug was approved by the Agency on July 25, 1997. There are no chemistry issues related to this supplemental application. The CMC regarding both drug substance and drug product are unchanged. The container/carton labels also remain unchanged. Based on the estimated increased usage of the drug, which may results in less than 1 ppb at the point of entry into the environment, the sponsor claimed categorically exclusion according to 21 CFR 25.31(b). The chemistry related information in the package insert remains unchanged. This supplement is recommended for approval from the CMC perspective.					
18. CONCLUSIONS AND RECOMMENDATIONS Approval is recommended from the CMC perspective.					
19. REVIEWER					
NAME Xiao Hong Chen, Ph.D.		SIGNATURE /S/		DATE COMPLETED 11-28-2000	
DISTRIBUTION	ORIGINAL NDA	DIVISION FILE	Reviewer: Xiao Hong Chen HFD-150	CSO: A. Staton HFD-150	Chemistry Team Leader: E. Duffy

HFD-810/DNDCl/JSimmons/HPatel